

Detachable Inflatable Sheath



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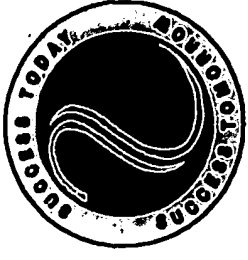
Detachable Inflatable Sheath

- **Key features for pre-deployment stent security**
 - Stent and stent edges will not catch while SDS is advanced through lesion or previously deployed stent
 - No stent movement while advancing through difficult lesions
 - Pullback into non-coaxial guide
 - No compromise to deliverability
 - Device can be integrated into current balloon inflatable SDS platforms
 - Device is E-beam compatible



Design Concept

- **Elastomeric sheath attached over SDS**
- **Low pressure inflation**
- **Sheath ruptures and retracts before stent edges expand**
- **Sheath rupture allows deployment of stent**



Design Concept

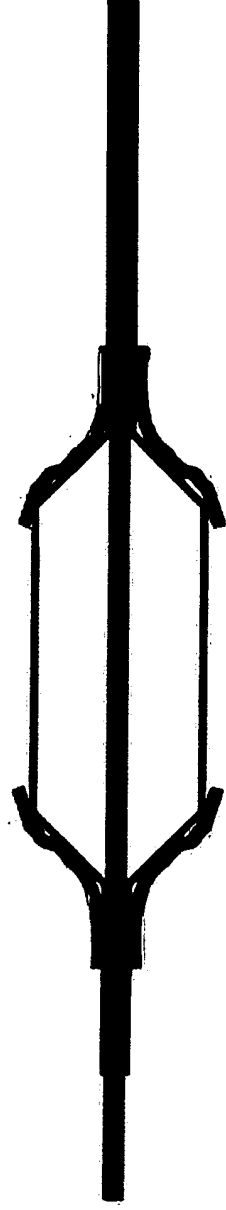
- Attach sheath over SDS
 - Score → Proximal seal → Stretch → Distal seal

Distal



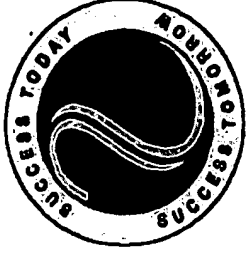
Before
Inflation

Sheath pulls back at perforated edges



During
Inflation

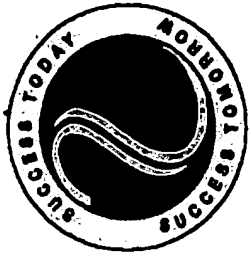
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Detachable Inflatable Sheath

- 5 mil thick sheath on 3.0 x 18 Duet
 - Pre-deployment profile 0.051”
 - Retraction at 2 atm
- Perforation

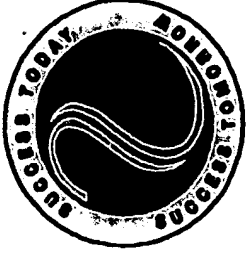


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Detachable Inflatable Sheath

- **Increased stent security over current SDS platforms**
- **Key distinctions and features**
 - Elastic, compliant sheath does not interfere with balloon inflation
 - Simple, inexpensive modification to SDS platforms
 - Readily manufacturable; minimal added development time
 - Minimal added profile and bulk
 - Complete protection over entire length of stent and stent edges
 - No added preparation or procedural time for interventionalist



Detachable Inflatable Sheath

- Recommendations for transfer to production
 - Optimize sheath rupture pressure
 - HPP to further reduce profile
 - Reduce sheath thickness
 - Optimize retraction
 - Separate lumen could allow sheath retraction prior to crossing lesion